



## Standard Operating Procedure (SOP)

<b>SOP Title</b>	NHS STAMINA assessments
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	<b>Name</b>	<b>Title</b>	<b>Signature</b>	<b>Date</b>
<b>Author</b>	Liam Bourke	Programme director		08/05/19
<b>Reviewer</b>	Derek Rosario	Chief Investigator	<i>DPR</i>	31/05/19
<b>Authoriser</b>	Liam Bourke	Programme director		31/05/19

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## 1.0 Purpose

This procedure is aimed at establishing safe and reliable working standards when collecting data at baseline and 12 weeks of follow-up for men with prostate cancer on ADT taking part in the STAMINA study.

This SOP describes how to collect, record, store and communicate data for the STAMINA study. This must be done in accordance with the specifications outlined in the study protocol.

## 2.0 Scope

This SOP is relevant for the NHS research nurse taking data from patients during STAMINA assessments and the SHU research co-ordination team.

## 3.0 Background

At both baseline and 12 weeks of follow-up, men will undertake an assessment of resting heart rate, resting blood pressure, body mass, height, chair sit-to-stand test. The research nurse will need to check existing co-morbidities and medications at baseline, and record any changes at the 12 week follow-up point.

## 4.0 Responsibilities

- The NHS research nurse carries overall responsibility for the collection, storage and communication of data to the SHU research team.
- The SHU research team have responsibility of ensuring data is stored and communicated with Nuffield Health sites accurately and securely.
- The NHS site PI carries overall responsibility for patient safety.

STAMINA baseline and 12 week follow-up data CRFs will be taken on NHS premises and originals stored in the NHS site file. Copies of CRFs should be emailed to the SHU STAMINA research team at [sth.stamina@nhs.net](mailto:sth.stamina@nhs.net)

## 5.0 Procedure

When booking the assessment appointments with the patient, they should be instructed to refrain from smoking, eating and consuming coffee for at least 3 hours, and drinking alcohol for 12 hours prior to measurement.<sup>1</sup>

### *Resting heart rate and blood pressure*

Participants should be rested at least 10 minutes in the recumbent position before taking measures. Heart rate and peripheral brachial systolic/diastolic blood pressure should be

measured using an automated BP monitoring device or sphygmomanometer with stethoscope (according to availability in clinic).<sup>1</sup>

#### *Body mass and height*

Body mass should be recorded in kg, with the patient removing their shoes and wearing light clothes they could exercise in. The patient should be asked to wear the same clothes for both baseline and 12 week follow-up assessments.

Height should be measured in meters, using a wall-mounted stadiometer or similar standardised height measuring equipment (according to availability in clinic).

#### *Chair sit-to-stand test*

A standardised 30 second chair sit to stand test<sup>2</sup> will measure lower limb physical function. For elderly individuals, the ability to stand up from a sitting position on surfaces of various heights is related to functional independence<sup>3</sup> and the measure of such ability has been considered as an index of thigh muscle strength.<sup>4</sup> Studies generally indicate that this test has good reproducibility ( $r > 0.8$ ) and demonstrates reasonable validity as related to similar measures of interest, e.g. knee extensor strength, stair climbing ability.<sup>2,4</sup>

- A chair should be placed against a wall before commencing.
- The patient is seated in the chair with his back flush against the chair back.
- He is then instructed to rise to a standing position from sitting (starting with his back flush against the chair back) and return to the sitting position as many times as possible in 30 seconds.
- Number of complete repetitions (sit to stand to sit = one repetition) in 30 seconds should be recorded on the baseline CRF. Only *completed* repetitions should be counted.

#### *Checking of existing co-morbidities and medications*

Self-reported existing co-morbidities and medications will be taken over the phone by the SHU research team, before patients attend their baseline assessment in the NHS. This will be documented using the 'Pre-exercise health questionnaire v1.0 13/11/18'. The SHU research team will send an electronic copy of this information to the research nurse ahead of the baseline appointment. The research nurse should check the self-reported information against NHS medical records and document any differences from medical records on the baseline CRF at both baseline and 12 weeks.

## **6.0 References**

1. Laurent S, Cockcroft J, Van Bortel L, et al. Expert consensus document on arterial stiffness: methodological issues and clinical applications. *Eur Heart J* 2006;27:2588-605.
2. Bohannon RW. Sit-to-stand test for measuring performance of lower extremity muscles. *Percept Mot Skills* 1995;80:163-6.
3. Corrigan D, Bohannon RW. Relationship between knee extension force and stand-up performance in community-dwelling elderly women. *Archives of physical medicine and rehabilitation* 2001;82:1666-72.

4. Csuka M, McCarty DJ. Simple method for measurement of lower extremity muscle strength. The American journal of medicine 1985;78:77-81.